

Statement of

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on

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## SUMMARY OF STATEMENT OF CARL E. GULBRANDSEN

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF, on whose behalf I appear. WARF is the patent management organization for the University of Wisconsin-Madison ("UW-Madison"). Founded in 1925 and one of the first organizations to engage in university technology transfer, WARF has had a significant impact on advances in scientific research and the welfare, health and safety of people in Wisconsin, this country and worldwide and is a recipient of the 2003 National Medal of Technology.

In 1980, under the leadership of this Subcommittee, Congress enacted the Patent and Trademark Law Amendments Act (commonly known as the Bayh-Dole Act), incorporating into law the cardinal principle that the public benefits from a policy that permits universities and small businesses to elect ownership of technology invented with federal funding and to become participants in the commercialization process. Today the list of inventions by individuals employed by U.S. universities is impressive. As patent owners, universities depend on a high quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer occurs and the public benefits. If the system is weakened, the public benefits are reduced.

The first line of defense against poor quality patents and slow decision-making is to provide the USPTO the fiscal resources that it needs to hire and train skilled examiners and implement effective electronic processing capabilities. Further steps remain. Diversion should be permanently barred. The USPTO should continue to implement its "Strategic Plan," which it can do in significant part through regulatory and administrative means. Several elements of the Strategic Plan require legislation, some of which are included in the Patent Act of 2005, for example, expanding the early publication of patents at 18 months and assignee filing.

The Patent Act of 2005 contains a number of other provisions that WARF supports as being beneficial for university technology transfer. Some changes to those provisions, however, are necessary. WARF supports the provision relating to limited post-grant opposition procedure, with the addition of appropriate curative amendments. Included in these amendments would be reasonable time limitations and no second window, full disclosure of the real party in interest, a broader range of the estoppel effect of the opposition, and support for the USPTO to implement without compromising its ability to examine and issue high quality patents. Moreover, the Subcommittee should ensure that the CREATE Act is preserved and that any CREATE Act amendments in the Patent Act of 2005 have the same effective date, same legislative history and same USPTO rule-making authority as Public Law No. 108-453.

The proposed legislation also contains a number of provisions which, if enacted without very significant changes, would retard the success of university technology transfer and the creation of vibrant new university spin-out companies. The specific provisions that WARF opposes include those regarding injunctions, limitations on continuation practice, and prior user rights. Finally for the benefit of universities and independent inventors, and to preserve our country's technological lead, WARF would prefer that the first-to-invent system be maintained. Nonetheless, WARF recognizes that some benefits are gained by harmonizing the U.S. patent system with the European and Japanese patent systems. However, certain statutory safeguards should be included. Mr. Chairman, thank you for your leadership, time and attention.

## STATEMENT

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee generally on the topic of patent law reform and specifically on the Patent Act of 2005. Thank you also for an important piece of legislation (the CREATE Act) processed into law last Congress by this Subcommittee under your leadership and that of the other ranking minority member, Mr. Berman, and numerous Committee cosponsors. Science today depends on collaborative research, and the CREATE Act will stimulate numerous inventive activities in the future.

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management organization for the University of Wisconsin-Madison ("UW-Madison"). I am making my statement today on behalf of WARF. WARF has not received any federal grants or engaged in any federal contracts or subcontracts that require reporting under House rules.

In addition to serving as Managing Director of WARF, I was recently appointed by the Secretary of Commerce to the Patent Public Advisory Committee of the United States Patent and Trademark Office ("USPTO"). I am also Vice President of the Public Policy Committee of the Association of University Technology Managers ("AUTM"). Finally, as a patent practitioner with over twenty years of experience in the private sector, I served as General Counsel of Lunar Corporation, a medical imaging company in Madison, Wisconsin; in law practice, I prosecuted patents and also litigated patent infringement cases representing independent patent owners and small businesses; and, as an adjunct faculty member, I have taught patent law at the University of Wisconsin Law School.

## **I. Background about WARF**

WARF was founded in 1925 and is one of the first organizations to engage in university technology transfer. It exists to support scientific research at the UW-Madison and carries out this mission by patenting university technology and licensing it to the private sector for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research. Over the past 80 years, WARF has contributed approximately \$750 million to UW-Madison to fund basic scientific research.

WARF's technology transfer successes have had a significant impact on advances in scientific research and has had profound and positive effects on the welfare, health and safety of people in this country and worldwide. Included among UW-Madison inventions patented and licensed by WARF are: Professor Harry Steenbock's invention of Vitamin-D, which essentially eradicated rickets as a childhood disease; Professor Karl Elvehjem's copper-iron complexes, which improved the physiological assimilation of iron in humans; Professor Karl-Paul Link's discovery of Coumadin®, the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide worldwide; Professor Charles Mistretta's digital vascular imaging technology, which enabled accurate diagnosis of blockage of the vessels of the heart; and Professor Hector DeLuca's Vitamin-D derivatives, which are widely used to treat osteoporosis, renal disease and other diseases. Year-by-year, the UW-Madison ranks in the top ten universities in terms of patents granted by the USPTO. As recognition of its excellence in technology transfer, WARF received in March of this year the National Medal of Technology, the highest award that can be conferred by the President of the United States to individuals and organizations making significant and lasting contributions to the country's economic, environmental and social well-being through the development and

commercialization of technology. WARF is the first university technology transfer office to receive this prestigious award, and I was proud to accept this honor personally from President Bush in the East Wing of the White House. Mr. Chairman, I believe that the honor bestowed upon WARF by the President is recognition by our government of the importance of university research and technology transfer to the economic health and well-being of our country. It is from this viewpoint that I am here testifying.

## **II. University Patent Licensing**

To understand WARF's position on the Patent Act of 2005 - and that of many other university technology transfer offices - an understanding of university patent licensing is necessary. In 1980, approximately 25 U.S. universities had technology transfer offices and no uniform federal patent policy existed. Today, more than 230 U.S. universities have such offices. In 1980, only a handful of patents were granted to universities. Today, universities are recipients of approximately four (4) percent of U.S. patents. This success has its roots in the Bayh-Dole Act.

In 1980, under the leadership of this Subcommittee and the House Science Committee, Congress enacted the Patent and Trademark Law Amendments Act (commonly known as the Bayh-Dole Act). *See* 35 U.S.C. §§ 200-212. This Subcommittee drafted into law the cardinal principle that the public benefits from public policy that permits universities and small businesses to elect ownership of technology invented with federal funding and to become participants in the commercialization process. After passage of the Bayh-Dole Act, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions. Today, the list of university inventions is indeed impressive. This list includes, among others, the following:

- The UW solution for the preservation of organs for transplant - University of Wisconsin - Madison;
- Lithography system to enable the manufacturing of nano devices - University of Texas - Austin;
- Rheumatoid arthritis relief - University of California - San Diego;
- Helping emphysema victims breath again - University of Florida;
- Effective Aneurysm Treatment - UCLA;
- Lice shampoo - Purdue Research Foundation;
- Google - Stanford University; and
- Turf grass - Rutgers University.

For a listing of more university innovations, *see* AUTM Licensing Survey: FY 2003.

These inventions, and many others, affect Americans in their daily lives, whether as hospital patients, farmers, employees in large and small businesses, scientists, students and entrepreneurs. The Bayh-Dole Act, so instrumental in the successful transfer of university technology to industry, is predicated on the conviction that universities must be able to pursue their mission of creating and disseminating knowledge in an open environment and, concurrently, protect their inventions through strong intellectual property laws. As patent owners, universities depend on a high quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer occurs and the public is benefited. If the system is weakened, the public benefit is reduced.

Mr. Chairman, based on our initial analysis of the Patent Act of 2005 (which has undergone several revisions since you shared a Committee Print several weeks ago), WARF is able to express support for many provisions. However, with all due respect for the proponents of change, several of the patent reform proposals represent a step backward for university patenting

and commercialization efforts. I believe that their passage would thwart the tremendous successes that universities have experienced in innovation. State-by-state, economic development, small businesses and jobs will be jeopardized.

### **III. Support the Needs of the USPTO**

In the past two decades, intellectual property assets have become vital to the performance of the U.S. economy. Continuing high rates of innovation and inventiveness are reflected in the patent law system, wherein patent grants are actively sought administratively, exploited commercially in the marketplace, and vigorously enforced in the federal courts. Since 1992, the number of applications in the USPTO has more than doubled to 400,000 applications annually (in fiscal year 2004) and, in 2005, the USPTO issued more patents than it did during the first four decades of American history. High quality patents serve as a measure of success. However, in recent years the patent office has been challenged financially and administratively resulting in an increase in pendency of applications and an occasional lapse in the quality of examination. These stresses on the patent office for the user translate into delays in negotiating and obtaining licenses to the pending applications and increases litigation costs when poor quality patents issue.

The first line of defense against poor quality patents and increasing patent pendency is to provide the USPTO, through the appropriations process, the fiscal resources that it needs to hire and train skilled examiners and implement effective electronic processing capabilities. Under the leadership of this Subcommittee, the initial step of providing the USPTO with adequate resources (with a temporary bar to fee diversion) was already accomplished in the Patent Fee Modernization Act. WARF supported that Act.

Further steps remain. Diversion should be permanently barred. In addition, the USPTO should continue to implement its “Strategic Plan,” which it can do in significant part, through regulatory and administrative means. Several elements of the Strategic Plan require legislation, some of which are included in the Patent Act of 2005: for example, expanding the early publication of patents at 18 months and assignee filing. WARF supports these proposals. Finally, as is suggested in “A Patent System for the 21<sup>st</sup> Century,” A Report of National Research Council of the National Academies (“NAS Report”), the USPTO should create an internal, multidisciplinary capacity to assess management practices and proposed changes, including an early warning system for new technologies. This Committee can also continue to play an important oversight role.

The patent law system, like a patient in a doctor’s office, needs to make certain lifestyle changes, but radical surgery is not necessary or required. Exercise of the “power of the purse” and vigilant oversight by the legislative branch, and administrative reforms by the executive, should serve to alleviate the need for some of the more radical reforms in the Patent Act of 2005.

#### **IV. A Threat to University Technology Transfer**

The Patent Act of 2005 contains a number of provisions that WARF supports as being beneficial for university technology transfer. Some changes to those provisions, however, are necessary. Most significantly, WARF supports the provision relating to limited post-grant opposition procedure, with the addition of appropriate curative amendments. Included in these amendments would be reasonable time limitations, no second window, full disclosure of the real party in interest, a broader range of the estoppel effect of the opposition, and support for the USPTO to implement without compromising its ability to examine and issue high quality patents.



As presently drafted, the post-grant opposition provision of the Patent Act of 2005, coupled with the removal of the estoppel effect afforded to reexaminations, will result in a university patent owner facing multiple third party patent challenges. A university could be forced to address the same issues regarding patentability during reexamination, post-grant opposition, and then litigation, all at significant expense. Such expense can be overly burdensome and force a university patent holder to abandon intellectual property rights rather than fight a protracted battle to secure protection for intellectual property developed by university investigators. Uncertainty about the rights secured through an issued patent will make licensing technology to the private sector for commercial development significantly more difficult for universities, thereby delaying the transfer of technology from lab to application and thwarting one of the primary purposes of the Bayh-Dole Act. For start-up companies, uncertainty will make it more difficult to attract investment dollars. Accordingly, the estoppel effect afforded reexamination should be maintained and certain limitations should be incorporated into the post-grant opposition process in order to stem abuse, avoid undo delays, and protracted uncertainty relating to the scope of patent protection.

I am also grateful to you, Mr. Chairman and Mr. Ranking Member, for your leadership and selflessness on enactment of the Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Public Law No. 108-453. I know that this important legislation on which I testified before this Subcommittee over three years ago would not have become law without your commitment to collaborative research and university technology transfer. I ask that you ensure that the CREATE Act be preserved and any CREATE Act amendments in the Patent Act of 2005 have the same effective date, same legislative history and same USPTO rule-making

authority as Public Law No. 108-453. In other words, there is no reason to change the substantive provisions of the CREATE Act.

The legislation before you also contains a number of provisions which, if enacted without very significant changes, will retard the success of university technology transfer and the creation of vibrant new university spin-out companies. Universities are dependent on a predictable and consistent patent system because a patent, in order to be licensed successfully to the private sector for commercial exploitation, must be dependable enough to stimulate necessary investments. As stated above, if the patent law is robust and strong, technology transfer occurs and the public benefits. If patent law is weakened, inventive successes by universities will diminish and the public benefit will similarly diminish. Accordingly, the specific provisions that WARF opposes include the following:

**1. Injunctions.** The Patent Act of 2005 contains a tilting of the playing field in favor of infringers over the interests of universities, small businesses and start-up companies. Section 7 requires a court to stay the injunction pending an appeal upon an affirmative showing that the stay would not result in irreparable harm to the patent holder and that the balance of hardships from the stay does not favor the patent holder. This language will result in appeals being made in most, if not all, patent infringement cases increasing the expense and in most instances, severely decreasing the benefit of the bargain the inventor makes with the government to obtain the right to exclude others from making, selling and using the invention in return for disclosing the invention to the public.

The right to exclude others from using the invention is fundamental to the patent bargain. A presumption in favor of injunctive relief is built into the process of patent infringement currently for good reason - injunctions respect this fundamental right to exclude. Any limits to

injunctive relief simply create incentives to infringe and to prolong litigation and, in fact, will potentially spawn additional litigation because companies will choose to forego up-front licensing and instead wait for a lawsuit to create what would be, in effect, a compulsory license. Such a situation would be especially difficult for universities because many are resource constrained and would have difficulty diligently pursuing their rights through litigation. In addition, the proposed changes would curtail the efforts of university spin-out companies to secure funding and develop innovative products and medicines because infringers will have less incentive to respect the patent rights of such companies. Consequently, investors will have less incentive to fund such innovative companies. This inevitable cooling effect on innovation would be particularly unfortunate considering that much of the success in promoting economic development through the Bayh-Dole Act has resulted from the successes of university spin-outs and small businesses.

**2. Limitations on Continuation Practice.** WARF opposes limiting continuation practice and believes such a change in the law would negatively impact universities and research laboratories. WARF, however, would support rulemaking authority in the USPTO to prevent abusive practices by patent applicants on continuation applications. University research is early stage research and the inventions coming from university research are most often not fully defined. Because of this, universities rely on filing robust initial applications that can be made more specific through additional claim language as the usefulness of a given discovery manifests itself, requiring that patent applications contain the broadest claims possible at the outset of prosecution will, in many instances, result in the real invention being lost. The loser in this “bet it all on the first roll” requirement is the public. The public deserves the benefit of the best inventions harvested from the supported research. Because university research is early stage the

flexibility to broaden claims through continuation practices is needed to identify the best invention to the public good.

**3. Prior User Rights.** WARF opposes the expansion of prior user rights. Expanded prior user rights would encourage innovations to be kept as trade secrets, a practice which is contrary to the fundamental premise of the U.S. patent system which rewards and encourages disclosure. The proposed broad scope of prior user rights favors trade secret practices and thus favors corporations at the expense of universities.

**4. First inventor to file.** The first-to-file system that exists in the rest of the world is a disadvantage to universities and independent inventors. Let me read what ProTon, the pan-European network of knowledge transfer offices has said about the European patent system. “The patent system in Europe, with its complexity and cost, is much less appropriate to university-based inventions than the U.S. system and acts as a barrier to innovation from public research. It lacks a grace period, a provisional patent system, a continuation-in-part (CIP) system and is several times more expensive. ProTon Europe is convinced that these differences account in large part for the much lower number of patented inventions coming out of public research in Europe.” (*Industry & Higher Education*, February 2005, page 6.) I believe that one of the reasons the United States is a technological leader is because we have a first-to-invent system. The first-inventor-to-file proposal would be a hardship for a vast majority of universities. Universities are open environments and universities rely on the advantage given to the true inventor by our present patent law system. Universities cannot afford a race to the USPTO.

For the benefit of universities and independent inventors and to preserve our country’s technological lead, WARF would prefer that the first-to-invent system be maintained.

Nonetheless, WARF recognizes that some benefits are gained by harmonizing the U.S. patent system with the European and Japanese patent systems. If we must harmonize, bear in mind that our system has certain advantages that must be preserved and are critical to our ability to innovate. After all, the U.S. is the world's leader in innovation.

For example, certain statutory safeguards are necessary. Such safeguards should include the means to promote public disclosure of new discoveries, maintain the blanket one-year publication rule that currently provides a one-year grace period, and protect the true inventor from misappropriation by parties who have not made a significant contribution to a claimed invention. The legislation should therefore, at a minimum, require an applicant to take an oath that he/she is an inventor or has been assigned the right to patent a given technology by the inventor and not leave such a determination to the discretion of the Director of the USPTO. In addition, the duty of candor imposed by patent law should specifically prohibit the misrepresentation of inventorship. Although a change to a "first-inventor-to-file" system would move U.S. patent practice closer to that of much of the rest of the world, any change to U.S. patent law still must recognize that under U.S. law and consistent with the U.S. Constitution, the right to patent goes to the inventor.

## **V. Related Issues**

The Bayh-Dole Act is widely recognized as successful beyond all expectations. It has been, and continues to be, an essential component of U. S. global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about Bayh-Dole and express the wish that their own countries would adopt such forward-thinking legislation. In fact, Japan's recent changes to its patent law were modeled on that of the U. S. Bayh-Dole Act. This committee should be proud of the role it played in passing

such successful, landmark legislation in this country. Now in its 25<sup>th</sup> year, we should think of ways to celebrate the Act's successes.

However, despite the undisputed successes of the Bayh-Dole Act, there are continued attempts to alter the Act in a manner that favors certain industries or groups. For example, the Patent Act of 2005 chips away at the value of university patents for the benefit of certain industries and, thereby, diminishes the good that can come from university technology transfer. I trust that this Committee in its wisdom will safeguard one of its most important legacies and oppose any legislation that compromises the demonstrated success of Bayh-Dole and its pivotal role in improving the welfare, health and safety of people in this country and worldwide.

## **VI. Conclusion**

Mr. Chairman, thank you again for your leadership, time and attention. In conclusion, I leave you with three recommendations:

- Unless a strong and compelling showing is made that change is necessary, maintain the patent law as it is presently enacted. Elements of the Patent Act of 2005 represent the interests of a narrow group of companies from one or two industry sectors and undermine the important policies upon which the Bayh-Dole Act is predicated. This country is the technology leader of the world in large part because of our Constitution which in Article I, Section 8, Clause 8 grants Congress the power “to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”
- If the Patent Act of 2005 is to move forward, then incorporate the modifications and safeguards suggested above to avoid some of its potential pitfalls. Continue to search for consensus, rather than special interest solutions.
- Finally, continue to protect university ownership of patents and technology transfer from erosion by amendments (either direct or indirect) that compromise its demonstrated successes.

The June 13, 2005, issue of *Business Week* features a cover story entitled

“Biotech, Finally,” detailing that biotechnology has finally come of age. The biotech revolution is actually an evolution that started on university campuses. According to the article; “it evinces the slow accumulation of decades of research” by academic researchers who pushed biotech forward. The endless cycle of academic research, technology transfer, collaborative research, and commercialization of cures by the private sector continue today into a golden age of drug discovery. Now is not the time for radical change.

If there are any questions, I will be pleased to answer them. Thank you.